K010271

APR - 3 2001

1. 510(k) Safety and Effectiveness Summary

ThinkingNet Medical Image Management and Review System

1.1 Demographic Information

1.1.1 Date Prepared

January 23, 2001

1.1.2 Submitter

Thinking Systems Corporation
1430 Serpentine Dr. S.
St. Petersburg, FL 33705
Phone: 727-906-4441
Fax: 727-867-7975
Email: tsc@speakeasy.org

1.1.3 Contact

JB Wang, CTO
Thinking Systems Corporation
6119 Prince Drive
San Jose, CA 95129
Phone: 408-865-0355
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Email: jwang_59@speakeasy.org

1.2 Device Name

1.2.1 Trade or Proprietary Name

ThinkingNet Image Management and Review System

1.2.2 Common Name

The common name used by FDA for these devices is **Picture Archive and Communications System.**

1.2.3 Classification Name

The FDA classification name is **Image Management Device** or **Picture Archiving and Communications System** (Section 892.2050). The product code is **LLZ.**

When the stand-alone software modules are marketed and used individually, NuPAX, NuLink, NuWEB, StoreSCP and base MDStation fall in the classification of **Medical Image Storage**

(Section 892.2010, product code LMB) and **Medical Image Communications** (Section 892.2020, product code LMD) devices.

1.3 Legally Marketed Predicate Devices

Thinking Systems **ThinkingNet** is substantially equivalent to **A.L.I. Technologies Inc. UltraPACS** (K925965/A) with A.L.I comPACS module (K963610) and **Applicare RadWorks Imaging Software** with Quality Control Module (K982862).

1.4 Device Description

ThinkingNet is intended to be used by authorized staff to perform medical image management, communications, storage, archiving and review.

ThinkingNet is composed of the following set of stand-alone software modules.

- **MDStation** is intended to be used by a doctor or technologist to review color and grayscale images from most diagnostic imaging modalities, such as CT, MRI, CR, Ultrasound, Nuclear Medicine, X-ray angiography and PET.
- **NuPAX** is intended to be used as personal or departmental image storage and archiving software. Modality scanners store images to it. The images can be retrieved later on by a review station, a modality scanner or a PACS. NuPAX can be configured to automatically forward images to a review station, PACS or Internet data center.
- **NuLink** is intended to be used as a connectivity gateway to import images from or export images to a supported proprietary digital medical imaging network such as ADAC Labs Pegasys network and Sopha/SMV SophyNet Nuclear Medicine network.
- **NuWEB** is a WEB Common Gateway Interface (CGI) to allow a user to review images stored in NuPAX with a regular WEB browser.
- **StoreSCP** is a reduced version of NuPAX for image storage. It does not have the image retrieval service.

These software components can be used together or individually on a Window 98, NT or 2000 based Intel Pentium compatible computer platform that satisfies the minimum requirements.

1.5 Intended Use

ThinkingNet is intended to be used by authorized staff to perform medical image management, communications, storage, archiving and review.

1.6 Comparison of Technical Characteristics

Both Thinking Systems **ThinkingNet** and Applicare RadWorks Medical Imaging Software are stand-alone software packages that can be used on more than one computer platform. As long as the minimum requirements are met, the user is free to choose his/own computer platform.

Thinking Systems **ThinkingNet**, Applicare RadWorks Medical Imaging Software (K982862) and ALI UltraPACS (K925965/A) offer substantially equivalent multi-modality image storage, archiving, transmitting and display features as listed below.

Feature	ThinkingNet	ALI UltraPACS	Applicare RadWorks
Image archiving	Yes	Yes	No
Image viewing	Yes	Yes	Yes
Transmitting images	Yes	Yes	Yes
Quality control	Yes	Yes	Yes
DICOM conformance	Yes	Yes	Yes
Window leveling	Yes	Yes	Yes
Zoom	Yes	Yes	Yes
Pan	Yes	Yes	Yes
Magnifying glass	Yes	Yes	Yes
Grayscale display	Yes	Yes	Yes
True color display	Yes	Yes	Yes
Palette color display	Yes	Yes	Yes
Grayscale invert	Yes	Yes	Yes
Annotation with marker and text	Yes	Yes	Yes
Tiled display format	Yes	Yes	Yes
MPR (Multi-planar reformatting)	Orthogonal (coronal, sagittal, transverse) orientations only	Yes	Yes
MIP (maximum intensity projection)	Attenuated/weighted maximum intensity projection	maximum intensity projection	maximum intensity projection
Pseudo color (color look-up table)	Yes	Yes	No
Study comparison	Yes	Yes	Yes
JPEG lossy image display	Yes	Yes	No
JPEG lossless image display	Yes	Yes	No

Feature	ThinkingNet	ALI UltraPACS	Applicare RadWorks
DICOM RLE image display	Yes	Yes	No
Using JPEG lossy compression for transmitting	Yes	Yes	No

Major differences between ThinkingNet and the legally marketed predicate devices.

Feature	ThinkingNet	ALI UltraPACS	Applicare RadWorks
Stand-alone software, user picks computer	Yes	No	Yes
Adjustable cine loops for multi-image series	No	Yes	Yes
Adjustable cine loops for multi-frame images	Yes	No	No
Frame-grab image acquisition	No	Yes	Yes
Non-DICOM proprietary digital imaging network interface	Yes	No	No
Image file formats supported	• DICOM 3.0 • Interfile 3.3 • ADAC Pegasys • Sopha/SMV Sophy ForthMacs format	DICOM 3.0	DICOM 3.0

The major difference between ThinkingNet and the legally marketed predicate devices are in multi-frame images display and non-DICOM image interface:

- The predicate devices are strong in displaying multi-image series whereas ThinkingNet is strong in displaying multi-frame images.
- The predicate devices use frame-grabber to acquire images from scanner devices that do not natively support DICOM whereas ThinkingNet has implemented proprietary protocols and file formats to interface with certain proprietary digital networks.

1.7 Conclusion

ThinkingNet is a medical image management device which has the same indications for use, target populations, and technical characteristics as the legally marketed predicate devices.

This premarket notification describes the characteristics of the ThinkingNet in sufficient detail to assure substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 3 2001

JB Wang
Chief Technology Officer
Thinking Systems Corporation
6119 Prince Drive
SAN JOSE CA 95129

Re: K010271
ThinkingNet
Dated: January 24, 2001
Received: January 29, 2001
Regulatory Class: II
21 CFR §892.2050/Procode: 90 LLZ

Dear Mr. Wang:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K010271

Device Name: ThinkingNet Medical Image Management and Review System

Indications For Use:

The **ThinkingNet Medical Image Management and Review System**, from Thinking Systems Corporation, Florida, USA, when installed on an appropriate computer platform, is intended to provide capability for the acceptance, transmission, display, storage, archival, and digital image processing of medical images. Options allow for additional capability, including transmission of images over local area or wide area networks, acceptance of digital images directly from different medical image modalities, displaying medical images with a Web browser, processing images, and 3D visualization.

(PLEASE DO NOT WRITE BELOW THIS LINE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter User _____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010271